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| APPLICATION NO.               | FILING DATE                 | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|-----------------------------|----------------------|---------------------|------------------|
| 10/583,489                    | 06/15/2006                  | Mustafa Demirbuker   | GTH-0003            | 3696             |
| 23413<br>CANTOR COL           | 7590 05/20/200<br>BURN, LLP | EXAMINER             |                     |                  |
| 20 Church Stree<br>22nd Floor |                             | BUSHEY, CHARLES S    |                     |                  |
| Hartford, CT 06103            |                             |                      | ART UNIT            | PAPER NUMBER     |
|                               |                             |                      | 1797                |                  |
|                               |                             |                      |                     |                  |
|                               |                             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|                               |                             |                      | 05/20/2009          | ELECTRONIC       |

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

|  | Application No.   | Applicant(s)  |  |  |  |
|--|---|---|--|--|--|
|  | 10/583,489  | DEMIRBUKER, MUSTAFA   |  |  |  |
| Office Action Summary  | Examiner  | Art Unit  |  |  |  |
|  | Scott Bushey  | 1797  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the c  | orrespondence address   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).   | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE   | lely filed the mailing date of this communication. (35 U.S.C. § 133). |  |  |  |
| Status   |   |   |  |  |  |
| 1) Responsive to communication(s) filed on <u>25 Ma</u>  | action is non-final.<br>nce except for formal matters, pro  |   |  |  |  |
| Disposition of Claims  |   |   |  |  |  |
| 4) Claim(s) 1-37 is/are pending in the application.  4a) Of the above claim(s) is/are withdraw  5) Claim(s) is/are allowed.  6) Claim(s) 1-4,6-8,10,16 and 18-37 is/are rejecte  7) Claim(s) 5,9,11-15 and 17 is/are objected to.  8) Claim(s) are subject to restriction and/or  Application Papers  9) The specification is objected to by the Examiner  10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the consequence of the propers are subjected to by the Examiner of the drawing sheet(s) including the correction is consequence of the property | vn from consideration.  d.  election requirement.  r.  epted or b) □ objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is objected to by the drawing(s) is objected to by the Edrawing(s) be held in abeyance. | e 37 CFR 1.85(a).<br>ected to. See 37 CFR 1.121(d).                   |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |   |  |  |  |
| Priority under 35 U.S.C. § 119   |   |   |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |   |   |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 6-15-06.  4) Interview Summary (PTO-413) Paper No(s)/Mail Date  5) Notice of Informal Patent Application 6) Other:   |   |   |  |  |  |

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#### **DETAILED ACTION**

#### Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-21, 35, and 36 in the reply filed on March 25, 2009 is acknowledged. Wherein the arguments therein are persuasive, the restriction requirement is withdrawn and all pending claims have been examined on the merits herein.

#### Claim Objections

2. Claims 33 and 35 are objected to because of the following informalities: In each of claims 33 and 35, "0,05" should be replaced by --0.05--. Appropriate correction is required.

### Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 19-21, 23-25, 32, 34, 36, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 19-21, the claims fail to provide any structural definition of the device which would facilitate or preclude the second inlet means being used to provide passage of a particular material.

Claims 23-25 are not in proper method format, since they fail to recite a manipulative step, since simple recitation of a material worked on by the device does

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not constitute a proper method step without also requiring manipulation of the material in a specific and discernible manner.

Claims 32 and 34 also fail to recite a manipulative step as required of any proper method claim.

Claim 36 recites an intended use of the device without further limiting the structure of the apparatus.

Claim 37 fails to either define the particles or further limit the method upon which claim 37 depends.

### Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 32, 34, and 36 provide for the use of a device or process, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 32, 34, and 36 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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## Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. Claims 1-3, 6-8, 10, 16, 18-23, 26-32, and 37 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by DeBoer, Jr. et al (Fig. 2; col. 1, line 54 through col. 2, line 14).

Applicant should note that the reference teaches a device and process of operating the device to form small particles of a substance, the device including a first inlet (2) for a liquid, a second inlet (3) for an atomizing fluid, a mixing zone formed by an adjustable interspace, the walls of which are movable relative to one another to adjust the volume of the interspace, one of the walls of the interspace being biased to move by means (12). Applicant should also note that the second inlet (3) is connected to the mixing means by second conduit chamber (4), while the first inlet means is connected to mixing means by first conduit means (8).

# Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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10. Claims 4, 24, 25, and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeBoer, Jr. et al.

DeBoer, Jr. et al (Fig. 2; col. 1, line 54 through col. 2, line 14) as applied above, substantially disclose applicant's invention as recited by instant claims 4, 24, 25, and 33-36, except for the biasing means being in the form of a spring, as recited by instant claim 4, the atomizing agent of the method of claims 24 and 25 being either in the form of a liquid jet or a medium at supercritical state, or the particles formed being of 0.05-10 microns in size and useable as a pharmaceutical substance.

With regard to the biasing means, it would have been obvious for an artisan at the time of the invention, to substitute a spring for the screw thread adjustment means, since as is well known within the art, a spring offers the added well known advantage of allowing the mixing area and outlet to temporarily enlarge to overcome an overpressurization due to clogging of the outlet. Whereas the chosen atomization agent, the particle size and the material of the particle would be dictated by the end use of the product desired, it would have been obvious for an artisan at the time of the invention, to choose any well known atomizing agent, including those as recited by instant claims 24 and 25, and to produce a particle of specific size and material makeup, as recited by instant claims 33-36.

## Allowable Subject Matter

11. Claims 5, 9, 11-15, and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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#### Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Bushey whose telephone number is 571 272-1153. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on 571 272-1166. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Scott Bushey Primary Examiner Art Unit 1797

/S. B./ 5-17-09

> /Scott Bushey/ Primary Examiner, Art Unit 1797